

19373. Adulteration and misbranding of solution of magnesium citrate (solution citrate of magnesia). U. S. v. Sterling Magnesia Co. (Inc.). Plea of not guilty. Judgment of guilty. Fine, \$100 and costs. (F. & D. No. 25037. I S. Nos. 05302, 08360, 08364.)

This action involved three interstate shipments of solution citrate of magnesia, a product recognized in the United States Pharmacopoeia. The law requires that an article sold by a name recognized in the pharmacopoeia conform to the standard of strength and quality provided by the said pharmacopoeia official at the time of investigation; or that if it differs therefrom, its own standard of quality and strength be declared upon the label. The article did not conform to the pharmacopoeial standard for strength, being deficient in magnesium oxide and citric acid, two of the essential ingredients; its own standard was not declared, since it was labeled "U. S. P. IX," its strength and quality fell below the requirements of the ninth revision of the pharmacopoeia; and portions labeled as containing 25 per cent less citric acid than the amount required by the pharmacopoeia, tenth (latest) revision, contained materially less citric acid than represented. The contents of the bottles, when measured, proved to be less than the volume declared on the labels.

On May 19, 1931, the United States attorney for the Northern District of Illinois, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for the district aforesaid an information against the Sterling Magnesia Co. (Inc.), Chicago, Ill., alleging shipment by said company in violation of the food and drugs act, in various consignments on or about September 8, 1928, May 15, 1929, and June 12, 1929, from the State of Illinois into the State of Wisconsin, of quantities of solution citrate of magnesia that was adulterated and misbranded. A portion of the article was labeled in part: "Rex Brand Eff. Solution Citrate of Magnesia." A portion was labeled, "Effervescing Solution of Citrate of Magnesia U. S. P. IX," also "Solution Citrate of Magnesia S. M. Co. U. S. P.," both statements appearing on the same label. On the bottle caps or crowns of all shipments appeared the statements: "Cont. Approx. 11½ Fl. Oz. Solution Citrate of Magnesia U. S. P. IX." In two shipments of the article stickers had been placed on the bottle bearing the following: "Not a United States Pharmacopoeia, Tenth Revision article; contains approx. 25% less citric acid to make it more palatable."

Adulteration was alleged in the information with respect to the product involved in one consignment for the reason that it was sold under a name recognized in the United States Pharmacopoeia, and differed from the standard of strength, quality, and purity as determined by the test laid down in the said pharmacopoeia official at the time of investigation, since it contained magnesium citrate corresponding to less than 1.5 grams of magnesium oxide per 100 cubic centimeters, acidity corresponding to less than 9.5 cubic centimeters of half-normal sodium hydroxide per 10 cubic centimeters, and total citric acid corresponding to less than 28 cubic centimeters of half-normal sulphuric acid per 10 cubic centimeters, whereas the said pharmacopoeia provided that solution of magnesium citrate (or solution citrate of magnesia, or magnesium citrate or citrate of magnesia, different designations for the same product) should contain in each 100 cubic centimeters magnesium citrate corresponding to not less than 1.5 grams of magnesium oxide; that it should contain acidity corresponding to not less than 9.5 cubic centimeters of half-normal sodium hydroxide per 10 cubic centimeters and should contain total citric acid corresponding to not less than 28 cubic centimeters of half-normal sulphuric acid per 10 cubic centimeters, and the standard of the strength, quality, and purity of the said article was not declared on the container thereof. Adulteration was alleged with respect to the product involved in the said consignment for the further reason that its strength and purity fell below the professed standard and quality under which it was sold in that it was represented to be solution citrate of magnesia which conformed to the standard laid down in the ninth revision of the pharmacopoeia, whereas it did not so conform since the said ninth revision provided that solution of magnesium citrate should contain magnesium citrate corresponding to not less than 1.5 grams of magnesium oxide per 100 cubic centimeters and total citric acid corresponding to 33 grams of citric acid per 350 cubic centimeters, whereas the article contained magnesium citrate corresponding to less than 1.5 grams of magnesium oxide per 100 cubic centimeters and total citric acid corresponding to less than 33 grams of citric acid per 350 cubic centimeters. Adulteration was alleged with respect to the product involved in the remaining two consignments

for the reason that it was sold under a name recognized in the United States Pharmacopoeia and differed from the standard of strength, quality, and purity as determined by the test laid down in said pharmacopoeia official at the time of investigation and its own standard of strength, quality, and purity was not declared on the container; for the further reason that it fell below the professed standard and quality under which it was sold in that it was represented to be solution citrate of magnesia which conformed to the standard laid down in the United States Pharmacopoeia official at the time of investigation, it was represented to conform to the standard laid down in the ninth revision of the said pharmacopoeia, and it was represented to contain approximately 25 per cent less citric acid than prescribed by the tenth (latest) revision of the pharmacopoeia, whereas it did not conform to the standard laid down in the pharmacopoeia official at the time of investigation, it did not conform to the standard laid down in the ninth revision and it contained less citric acid than represented, i. e., the two consignments which were labeled as containing approximately 25 per cent less citric acid than prescribed by the tenth revision of the pharmacopoeia containing 32.3 per cent and 33.4 per cent less citric acid than prescribed by the tenth revision.

Misbranding was alleged with respect to the product involved in one consignment of the article for the reason that the statements, "Solution Citrate of Magnesia U. S. P. IX" and "Cont. Approx. 11½ Fl. Oz.," borne on the label, were false and misleading since the article did not conform to the standard laid down in the United States Pharmacopoeia, ninth revision, and the bottles contained less than 11½ ounces of the article. Misbranding was alleged with respect to the product involved in the remaining two consignments for the reason that the statements, "Solution Citrate of Magnesia," on the label of one of the said consignments and the statement, "Solution Citrate of Magnesia U. S. P.," on the label of the other of the said consignments and the statements, "Solution Citrate of Magnesia U. S. P. IX," "Not a United States Pharmacopoeia Tenth Revision article contains approx. 25% less citric acid," and "Contains 11½ Fl. Oz.," on the labels of both of the said consignments were false and misleading, since the article did not conform to the standard laid down in the United States Pharmacopoeia official at the time of investigation; it did not conform to the standard laid down in the ninth revision of the said pharmacopoeia, it contained less citric acid than represented, and the bottles contained less than 11½ fluid ounces of the article.

On January 25, 1932, a plea of not guilty having been entered on behalf of the defendant company, the facts were submitted to the court who made a finding of guilty and imposed a fine of \$100 and costs.

ARTHUR M. HYDE, *Secretary of Agriculture.*

19374. Adulteration and misbranding of Acco-balm. U. S. v. 55 Large Packages, et al., of Acco-balm. Default decree of condemnation, forfeiture, and destruction. (F. & D. No. 26466. I. S. No. 30516. S. No. 4726.)

Examination of the drug product Acco-balm having shown that the article was represented to be antiseptic, whereas it was not, also that the labeling contained unwarranted curative and therapeutic claims, the Secretary of Agriculture reported the matter to the United States attorney for the District of Massachusetts.

On June 5, 1931, the United States attorney filed in the District Court of the United States for the district aforesaid a libel praying seizure and condemnation of 55 large packages and 40 small packages of the said Acco-balm, remaining in the original unbroken packages at Boston, Mass., alleging that the article had been shipped by the A. C. Clark Co. (Inc.), from Brattleboro, Vt., in part on or about April 18, 1931, and in part on or about May 12, 1931, and had been transported from the State of Vermont into the State of Massachusetts, and charging adulteration and misbranding in violation of the food and drugs act as amended.

Analysis of a sample of the article by this department showed that it consisted essentially of zinc oxide, boric acid, and a trace of an essential oil incorporated in a petrolatum base. Bacteriological examination showed that the article was not antiseptic.

It was alleged in the libel that the article was adulterated in that it was sold under the following standard of strength, namely, antiseptic, and its strength fell below such professed standard, since it was not antiseptic.